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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,412	10/27/2000	Haskell E. Mullins	56108USA1A.002	5638

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EXAMINER
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WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 08/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/698,412

Applicant(s)

Mullins et al.

Examiner

Joseph Weiss

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 14, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-21-22, 24-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burstroem (FOA Report C40208-C1(C2) in view of Pasternack (DE 26-52-136-B1)

Burstroem substantially discloses the instant application's claimed invention to include a qualitative respirator fit testing system comprising a plurality of test stations (note fig 3 & cartoon on cover, specifically the human head height openings to the chamber) that utilizes aerosol generation for qualitative fit testing, but does not explicitly disclose an automated aerosol generator in fluid communication with each test station. However, Pasternack disclose such (10). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Pasternack and used them with the device of Burstroem. The suggestion/motivation for doing so would have been to insure optimal test aerosol was delivered to the test station. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

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Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 22, the suggested device substantially discloses the instant application's device, but does not disclose the provision of a plurality of aerosol generators, dedication one station to each test station, i.e. the duplication of a known part for a known purpose. However, at the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have duplicated the number of aerosol generators to match the number of test stations. The suggestion/motivation for doing so would have been to process more personnel for mask test fit more quickly. Therefore it would have been obvious to ob duplicated a known part for a known purpose to obtain the instant application's claimed invention.

Furthermore, it is noted that applicant's specification does not set forth this duplication of a known part for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the duplication of a known part for a known purpose to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

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In regards to claim 24, the suggested device discloses an aerosol generator in fluid communication with at least two test stations.

In regards to claim 25, the suggested device discloses the use of a respirator fit test hood for each test station. (Note the test stations and structure of Burstroem serve as a "hood")

In regards to method claims 1-20 & 26-36, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 21-22, 24-25, with specific reference to the various method steps noted as follows:

In regards to claims 1, 15, 16-17, 27 the suggested device discloses receiving test subject(s) feedback from testing, to include feedback regarding "sensitivity" aerosols and when "remote" (Note Burstroem's use of Qualitative Mask Test Fitting QMTF).

In regards to claims 2-3, 7, 34 the suggested device discloses simultaneous testing and prompting of test subjects at the stations. (Note Burstroem's use of Qualitative Mask Test Fitting QMTF, Note Appendix c of DA Pam 40-8 regarding what the industry standard/definition of "Qualitative test fitting is defined, contains inherently implicates)

In regards to claim 6-7, regarding the use of predetermined time intervals, the suggested device discloses such (See Burstroem's notation of number of personnel to be tested w/in a hour, note disclosure of Pasternack regarding control and operation of device 10))

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In regards to claim 8, the suggested device is fully capable of delivering different amounts of aerosol to different test stations/subjects.

In regards to claims 9-10, 19-20, 28-29 the suggested device discloses storage of results in a database (See disclosure of element 15 of Pasternack, use/creation of a “data log”).

In regards to claim 11, 30 the suggested device discloses monitoring of the test stations during testing. (See disclosure of element 15 of Pasternack, use/creation of a “data log”).

In regards to claim 13-14, 32-33 the suggested device discloses the prompting of test subjects to perform activities during testing. (Note Burstroem’s use of Qualitative Mask Test Fitting QMTF, Note Appendix c of DA Pam 40-8 regarding what the industry standard/definition of “Qualitative test fitting is defined, contains inherently implicates)

In regards to claim 18, the suggested device is fully capable of selectively shutting off testing of an individual test subject. (Note the feedback sensor of Pasternack (13) which controls aerosol generator 10)

In regards to claim 26, the suggested device is fully capable of remote automated test fitting.

In regards to claims 35 & 36, the suggested device is fully capable of being provided at a remote location in multiples for simultaneous operation.

In regards to claims 37 & 38, the suggested device is fully capable of delivering repeatable selected amounts of test aerosol to a test station or delivering different selected amounts of test aerosol to at least two different test stations using an automated aerosol generator.

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3. Claims 12, 31 & 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burstroem & Pasternack as applied to claims 1 & 26 above, and further in view of Tilley (US 6435009).

In regards to claim 12, 31 & 39 the suggested device/method substantially discloses the instant application's claimed invention, but does not explicitly disclose the capturing and storage of images. However, Tilley disclose such (See Tilley disclosing the monitoring of screens 272-282 & 370-380 and 398 and the data depicted on the screen being "captured" in memory, the data log). The references are analogous since they are from the same field of endeavor, the testing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Tilley and used them with the suggested device/method. The suggestion/motivation for doing so would have been to document the mask fit data for medical records/exposure/documentation purposes. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

4. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burstroem & Pasternack as applied to claim 21 above, and further in view of Loedding et al. (US 5156776).

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The suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a nebulizer as the aerosol generator. However, Loedding disclose such (See element 2). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Loedding and used them with the suggested device. The suggestion/motivation for doing so would have been to because use of a nebulizer falls within the scope of an aerosol generator and because use of a nebulizer produces an optimal and uniform aerosol cloud. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 1-36 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. "An Automated Aerosol Generator to Reduce Variability in Qualitative Fit Testing of Respirators" KP Fennelly et al American Journal of Respiratory and Critical Care medicine Vol.



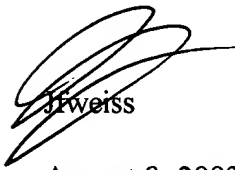
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159, Supp #3 pages PA 615 DTD 1999 is still being sought for evaluation. If applicant has access to such he may wish to avail himself to this document for review and consideration.


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



August 8, 2003



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